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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/039,869	11/09/2001	Douglas C. Wallace	50-96B	8369
23713	7590	10/22/2003	EXAMINER	
GREENLEE WINNER AND SULLIVAN P C			GITOMER, RALPH J	
5370 MANHATTAN CIRCLE			ART UNIT	
SUITE 201			PAPER NUMBER	
BOULDER, CO 80303			1651	

DATE MAILED: 10/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/039,869	WALLACE ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Ralph Gitomer	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on 11/9/97
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☐ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)                      4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_                      6) ☐ Other: \_\_\_\_\_

This application is a continuation of 09/454,126, please  
update the specification regarding related cases. Priority is  
granted to 9/6/1996. Please provide a date of publication of #13  
5 Mattson M.P. article listed in the IDS of 3/7/2002. The sequence  
requirements have been met.

Claims 1-8 are rejected under 35 U.S.C. 112, first  
paragraph, as based on a disclosure which is not enabling. A  
10 number of features are critical or essential to the practice of  
the invention, but not included in the claim(s) is not enabled by  
the disclosure. *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA  
1976).

It is difficult to determine what the actual invention may  
15 be by reading the specification as originally filed. On page 15  
lines 22-28, keeping the knockout mice alive long enough to  
develop neuropathy by administering MntBAP may be novel. On page  
16 the mice are reported to survive up to about 18 days and  
exhibit neuron degeneration without such treatment. This is in  
20 conflict with the data presented in Table 4 on page 30 which  
indicates the mice live about 7 days without treatment.

In any case, it would appear to be essential to the  
invention to administer a free radical scavenger compound to the  
mice prior to the claimed screening.

Claims 1-8 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

On page 17 first full paragraph, ¶The increased neurological effectiveness of Euk-8 in comparison to MntBAP indicates that it is possible to screen different compounds rapidly and easily for effectiveness in preventing free radical mediated disorders of the central nervous system in the particular MnSOD (-/-) mouse exemplified herein.¶ On page 19 lines 15-18, ¶Thus, animals which have been treated with an antioxidant such as MntBAP or Euk-8 can be used for the screening of antioxidants which will prevent or delay the onset of the mitochondrial myopathy phenotype in skeletal muscle.¶ On page 30 Table 4 shows the lifespan of mice untreated, treated with Euk-8 and MntBAP.

No screening of any compounds is shown in the specification as originally filed. It would appear, but is unclear, that the administration of KNOWN antioxidant compounds prior to the administration of test antioxidant compounds is essential to the claimed invention. However, no such multiple administration is shown and therefor no compounds are found which have antioxidant activity which is what is presently claimed.

Applicant's arguments filed 4/17/01 have been fully considered but they are not persuasive.

Applicants argue that the claims clearly state the invention. The homozygous mice generated by Li were used to describe the claimed methods in the present application.

It is the examiner's position that the specification must provide written description and enablement for the claimed invention and it does not. The above rejection is made under 35 USC 112, first paragraph, not second paragraph. The above rejection is not directed to obtaining the mutant mice. And, importantly, it would appear following Li, mice would not live long enough to perform the presently claimed invention.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the

inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103<sup>®</sup> and potential 35 U.S.C. 102(f) or (g) prior art under 35

5 U.S.C. 103(a).

Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Li.

Li (Nature Genetics) entitled "Dilated Cardiomyopathy and Neonatal Lethality in Mutant Mice Lacking Manganese Superoxide  
10 Dismutase" teaches in the abstract, mutant mice which produce inactive MnSOD. On page 376 column 2 first paragraph, the animal model will be useful for studies on oxygen radical induced tissue injury.

The claims differ from Li in that they are directed to  
15 testing unknown compounds where Li teaches studying tissue injury with known compounds.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to test unknown compounds because Li teaches the transgenic mouse can be used for studying  
20 antioxidants in general and to study the antioxidants instead of their effects is an obvious variant.

Regarding the specifically claimed compounds MntBAP and Euk-8, it would have been obvious to one of ordinary skill in the art at the time the invention was made to employ any known SOD  
25 mimetic for its known function and both are known SOD mimetics.

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Applicant's arguments filed 4/17/01 have been fully considered but they are not persuasive.

5 Applicants argue that the specification teaches the neonates are maintained which is not shown in the cited reference. The goal of Li was to study MnSOD and it is merely stated in general terms that these animals would be useful for studies in oxygen radical induced tissue injury. This does not suggest using the animals for testing compounds of antioxidant activity. The invention is possible because it was discovered that MntBAP affects the life span of the mice.

10 It is the examiner's position that Li teaches homozygous mice are useful for the presently claimed invention. Our animal model will be useful for studies on mitochondrial defect-related cardiomyopathy, oxygen radical-induced tissue injury, cytokine-mediated cellular responses and cellular differentiation.

15 The present claims contain no limitations directed to maintaining the neonates and the discovery of how to do this is entirely independent to what is claimed.


20 Claims 6 and 7 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 6 is not understood and may have a typo. In claim 7, the observations may be intended to be the observing. Also, detection may be intended to be detecting.

5 Any inquiry concerning this communication or earlier  
communications from the examiner should be directed to Ralph  
Gitomer whose telephone number is (703) 308-0732. The examiner  
can normally be reached on Tuesday-Friday from 8:00 am - 5:00 pm.  
The examiner can also be reached on alternate Mondays. If  
10 attempts to reach the examiner by telephone are unsuccessful, the  
examiner's supervisor, Michael Wityshyn can be reached on (703)  
308-4743. The fax phone number for this Art Unit is (703) 872-  
9306. Any inquiry of a general nature or relating to the status  
of this application should be directed to the Group receptionist  
15 whose telephone number is (703) 308-1235. For 24 hour access to  
patent application information 7 days per week, or for filing  
applications electronically, please visit our website at  
www.uspto.gov and click on the button Patent Electronic Business  
Center for more information.

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Ralph Gitomer  
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